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Original Article

Efficacy of balloon kyphoplasty in pain management of vertebral compression fractures

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Abstract

Aim: Vertebral compression fractures lead to pain, significant spinal deformity and functional disability that severely limit the health-related quality of life. Although most patients respond to conservative treatment, it has been shown that more than 40% of patients do not achieve the desired reduction in pain within 1 year of onset of symptoms. Percutaneous balloon kyphoplasty is often used to relieve symptoms and accelerate the recovery of function. The aim of this study is to evaluate the pain and functional outcomes of patients treated with percutaneous balloon kyphoplasty.

Material and Methods: Data of 113 patients who underwent percutaneous balloon kyphoplasty with the diagnosis of vertebra compression fracture between January 2015 and June 2019 were scanned. Preoperative and postoperative Numeric Rating Scale scores and Oswestry Disability Index (ODI) scores with complications were evaluated.

Results: 113 patients with 154 vertebral fractures were treated. 86 were female and 27 were male. The mean age was 76.8 years. L1 (n=29) and Th12 (n=31) vertebral fractures were the most common. The mean duration of the procedure was 65.93 minutes, and the mean volume of cement was 5.02 ml. Cement leakage was observed at 12 cases. Permanent neuromotor deficits or mortality was not observed at any of the patients. Following percutaneous balloon kyphoplasty, the NRS and ODI scores significantly improved at the 6th month follow-up compared with preoperative scores, the NRS and ODI scores before the procedure were 8.8 and 49.2 whereas the postoperative NRS and ODI were 2.2 and 18.1, which is.

Conclusion: Percutaneous balloon kyphoplasty is an effective procedure to control pain and improve health related quality of life. This method has the advantage of improving and restoring the vertebral height and kyphotic deformity in osteoporotic or pathological vertebral compression fractures.

Keywords: Balloon kyphoplasty; vertebrae; pain; outcome

INTRODUCTION

Vertebral compression fractures lead to acute or chronic pain, significant spinal deformity and functional disability that severely limit the health-related quality of life, therefore increase health care costs (1,2). Every year an estimated number of 1,700,000 vertebral compression fractures (VCFs) are reported worldwide, which tends to rise with elder age (3). The most common causes of VCFs are primary (postmenopausal) or secondary osteoporosis (senile, malignancies, gastrointestinal system diseases, steroid use) leading to low bone mass and disruption of microstructure of bony tissue (3). However benign or malign infiltrating tumors can also cause VCFs (4).

Conservative treatments such as analgesic drugs, bed rest and braces or corsets, and surgical vertebral cement [polymethylmethacrylate (PMMA) injection are the most commonly used methods for the treatment of compression fractures. However non-surgical treatment requires prolonged immobilization that may exacerbate osteoporosis; may cause mental status changes due to severe analgesic use; may increase the risk of pneumonia, pressure ulcers and thromboembolic events; therefore increases the risk of fracture-related morbidity and mortality by 50 % (5-7).

The minimally invasive surgical techniques of percutaneous vertebroplasty (PVP) and percutaneous balloon kyphoplasty (PBCP), which are cement applications to the vertebra, have become the main treatment options in the treatment of vertebral compression fractures. PBCP was first performed in 1998, with the aim of suppress and compressing the bone with the help of a balloon to reduce the fracture and restore the height of the vertebrae (1,8). Two bone-compressing balloons placed on both sides create a space in the vertebrae that the high-density bone

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cement (PMMA) can fill manually in a controlled manner with low pressure. Unlike PVP, the aim of PBCP is not only fracture fixation and stabilization, but also to correct and maintain spinal deformity, thereby reducing the negative burden of the vertebral compression fractures (1,2,9).

The aim of this study is to evaluate the pain and functional outcomes of PBCP in patients whose symptoms lingered or increased during conservative treatment.

MATERIAL and METHODS

Ethics Approval and Patient Consents

This is a retrospective clinical study that evaluates patient symptoms, neurological and imaging findings, with complications before and after treatment. This study was approved by Başkent University Institutional Review Board (Project no: 94603339-604.01.02/ 44412) and supported by Başkent University Research Fund. Informed consent was obtained from all the participants of the study.

Patient Selection

A retrospective data review of 113 patients (154 vertebrae) who underwent percutaneous balloon kyphoplasty for vertebral compression fractures between January 2015 and June 2019 at our hospital was performed.

Inclusion criteria were; severe back/lumbar pain affecting daily life less than eight weeks, tenderness by palpation in physical examination, normal neurological examination, patients showing limited high signal intensity in T2-weighted and short tau inversion recovery (STIR) weighted sequences and diffuse low signal intensities in T1- weighted sequences at magnetic resonance imaging (MRI) studies without any medulla spinalis or nerve root compression. Patients with symptoms lasting more than 8 weeks, chronic compression fractures, neurological deficits, MRIs revealing a fracture of the posterior segment of the vertebrae or a bone fragment expending into the spinal canal, were excluded from the study.

Clinical Evaluation

Preoperative and postoperative pain intensity of the patients was evaluated between 0 and 10 using Numeric Rating Scale-NRS, with 0 being the lowest score accepted as no pain, and 10 being the highest score with the worst experienced pain(10). The quality of life and functional ability of the patients was evaluated using the Oswestry Disability Index (ODI) scale. ODI consists of a questionnaire that contains 10 topics. These items question the severity of pain, the ability of self-care, the ability to lift and carry, the ability to walk, the ability to sit, the ability to stand, the ability to travel, social life and sleep quality. Under each item there are six statements that mark the appropriate one for the patient's condition. Each question in the questionnaire is scored on a scale of 0–5, with 0 as no disability and 5 as the most severe disability. Then the total score is calculated, is multiplied by two, and the result is expressed as a percentage. The maximum score is ৳100৳ and the minimum score is ৳0৳. Disability degree increases as the total score increases (11). Patients' preoperative, early postoperative and 3rd month follow-up scores were evaluated.

Surgical Technique

All procedures were performed in the operating room, with sterile conditions, under sedoanalgesia and local anesthesia. In multilevel applications, general anesthesia was preferred in patients who were difficult to cooperate and predicted to be mobile. 1 gr of cephazolin sodium (1 gr) was administered intravenously and all patients were placed in the prone position. The affected vertebral body was identified with anterior-posterior (AP), oblique and lateral radiographic views on C-arm fluoroscope. With a transpedicular two-sided approach, 11-gauge Jamshidi biopsy needles were inserted percutaneous on AP imaging, entering the upper outer margin of the pedicle ring into the fractured vertebral corpus. Under the guidance of two Kirschner wires, two cannulas were placed in the posterior half of the vertebral body. As in routine procedure, biopsies were taken from the vertebral bodies of all patients and sent for pathological examination. Both balloons were inflated simultaneously guided by the lateral views of C-arm fluoroscopy until the vertebral height was observed to restore. After deflating the balloons, according to the clinical situation, 2-5 mL of PMMA was injected into the thoracic vertebrae and 3-8 mL into the lumbar vertebrae via the pedicles. Simultaneous anterior-posterior and lateral view C-arm fluoroscopies showed cement dispersion. The procedure was terminated if an overflow of the cement was observed. The patients were followed in the clinic for one day, than discharged.

Complications

Complications were noted as local cement leakage, pulmonary embolism, radiculopathy, infection and adjacent segment compression fracture.

Statistical Analysis

Clinically, preoperative, early postoperative and 6 months follow-up records of pain changes, functional and radiological results, and complications were evaluated. Statistical analysis was performed using SPSS for Windows© software, version 22.0 (Armonk, NY, USA).

RESULTS

In this study, a total of 154 fractured vertebrae in 113 patients between levels Thoracic 6 to Lumbar 5 were evaluated. The mean age was 76.8±9.77, ranged from 42 to 96 years, and the mean follow-up was 26.42 ± 4.32 months (6-50 months). 76,1% of the patients were female. 95 of 113 patients had fractures due to primary and 18 patients had fractures due to secondary osteoporosis (8 patients with senile, 7 patients with malignancy) (Table 1).

Mostly under sedoanalgesia, in a mean time of 65.9±27.50 min (range 30-210 min), a mean injection of 5.034±1.25 mL PMMA was performed in 154 vertebrae corpus, 98 of which were at lumbar and 56 at thoracic level. Simultaneous PBKP were performed in 21 patients, with 13 cases for 2 levels, 5 cases for 3 levels, and 3 cases for more than 3 levels.

Table 1. Demographic features of the patients

	Patient (n=113)
Age (years, mean ± SD)	76.8 ± 9.74
Gender (n, %)	
Female	86 (%76.1)
Male	27 (%23.9)
Follow-up (months, mean ± SD)	26.42 ± 4.32
Primary osteoporosis (n, %)	95 (%84.1)
Secondary osteoporosis (n,%)	18 (%15.9)
Senile	8 (%7.1)
Multiple Myeloma	5 (%4.4)
Amyloidosis	1 (%0.9)
Chronic Renal Failure	1 (%0.9)
Breast Cancer	1 (%0.9)
Chronic Myeloid Leukemia	1 (%0.9)
Liver Transplantation	1 (%0.9)

SD: standart deviation

Lumbar 1 vertebra was the most common single compressed vertebra (n=29), whereas thoracic 12 vertebrae compression was found as the most common fractured vertebra at multi-level fractures (n=31). No serious systemic or neurological complications were observed in any of the patients. In 12 cases (10.6%), radiologically post-procedural cement leakage into the intervertebral space or spinal canal was observed. Two patients suffered from urinary tract infection. Adjacent segment fractures were not detected in any patient at the 6th month follow-up. No difference between preoperative and postoperative physical and neurological examinations was found. Table 2 demonstrates the summary of PBKP procedures that were performed in this study.

Statistically significant decrease in NRS and ODI scores in the early postoperative and 3rd month follow-up after the intervention compared to preoperative scores were reported. Preoperative mean NRS was 8.82±0.89 (range, 7-10), whereas early postoperative NRS was 2.25±0.99 (range, 1-5) and 6th month follow-up NRS was 2.29±0.90 (range, 1-5) (p=0.001, p=0.766 respectively). Also, preoperative mean ODI was 49.24±5.58 (range, 34-62), however early postoperative ODI significantly improved to 18.17±4.86 (range, 10-26) with a 6th month follow-up ODI of 19.16±4.34 (range, 10-28) (p=0.001, p=0.107 respectively) (Table 3).

Table 2. General information about percutaneous balloon kyphoplasty procedure

	Patient (n=113)
Anesthesia type	
General	7 (%6.2)
Sedoanalgesia	106 (%93.8)
PMMA volume (mL, mean ± SD)	5.034 ±1.25
Duration of Surgery (min, mean± SD)	65.93 ± 27.5
Entrance side	
Bilateral	110 (%97.3)
Right	2 (%1.8)
Left	1 (%0.9)
Simultaneous fracture	
Single	92 (%81.4)
Multiple	21 (%18.6)
Vertebral level	n=154
L1	29 (%18.8)
L2	26 (%16.9)
L3	24 (%15.6)
L4	11 (%7.1)
L5	8 (%5.2)
Th6	3 (%1.9)
Th7	2 (%1.3)
Th8	3 (%1.9)
Th9	3 (%1.9)
Th10	6 (%3.9)
Th11	8 (%5.2)
Th12	31 (%20.1)
Complications	
Cement leakage into intervertebral disc	7 (6.2%)
Cement leakage into spinal canal	5 (4.4%)
İnfection	2 (1.76%)
None	99 (87.6%)

PMMA: Polymethylmethacrylate, min: minutes, Th: thoracic, L: lumbar

Table 3. Effects of PBKP procedure on pain and quality of life

	Preoperative	Early Postoperative	6th Month Follow-up
NRS	8.82±0.89	2.25±0,99	2.29±0,90
ODI	49.24 ± 5.58	18.17 ± 4.86	19.16 ± 4.34

NRS: Numeric Rating Scale, ODİ: Oswestry Disability Index

DISCUSSION

The main purposes in treatment of symptomatic vertebral compression fractures are; pain control, vertebral height and kyphotic angulation correction, and quality of life improvement(12). Early intervention is essential to reduce morbidity and mortality in these mostly elderly patients.

Vertebral compression fractures are predominantly in osteoporotic older women, however incidental infiltrative tumor-related fractures in 10-15% of the cases are reported in the literature(13). Vertebral metastases are frequent from primary breast, prostate, lung, bladder, and thyroid cancers, with a reported rate of 30–95%(14). Also some cancer treatments or the cancers themselves like multiple myeloma can cause generalised bone loss or osteolytic lesions in the vertebrae that can lead to fractures(15). Although the rate of vertebral compression fractures secondary to malignancy was lower in our study compared with the literature, with a rate of 6.2 % (7/113) and as multiple myeloma being observed the most (4.4%), multiple vertebral fractures due to malignancies were more frequent.

In their study Belkoff et al. reported that 2 mL PMMA application into the vertebral corpus during PBKP could be enough for the restoration of vertebral corpus strength. However, they recommended 4 mL cement injection into the thoracic vertebra and 6 mL cement injection into the lumbar vertebra to restore stiffness(16). In this present study a mean volume of 5.034±1.25 mL PMMA was injected into the fractured vertebra, which is similar to the literature.

Bilateral PBKP has been considered as the mainstay approach, on the other hand, lately unilateral PBKP has become popular since it is reported to provide numerous benefits such as shorter operation times, less radiation exposure, and lower complication rates (17) . We performed bilateral PKBP in our patients as first choice of treatment, however due to unexpected conditions we had to use unilateral approach in 3 patients. No difference was observed at follow-up between uni/bilateral PKBP patients.

The complications of PBKP were reported as; cement leakage, new or incident adjacent segment fractures, pulmonary embolism, spinal cord compression, radiculopathy, infections, mortality(1). Bouza et al. reported 18.3% of cement leakage at their meta-analysis about safety of balloon kyphoplasty [(18). The most observed complication in our patients was cement leakage (10.6%), however none of these caused any neurological deficits. Therefore, PBKP showed be a more reliable method in terms of cement leakage than vertebroplasty, which was similar to the reported literature. The only other reported complication was urinary tract infections in two patients.

Pain treatment and supportive care in osteoporotic or metastatic spinal disease may help prolong the average lifespan for patients and strengthening the fractured vertebra with cement application techniques have long been used to promote early patient mobilization. The aim of this study was to evaluate the clinical results of PBKP on pain relief and quality of life. All patients were followed for at least 6 months. The referral findings were compared to postoperative and follow-up findings with existence of complications. A statistically significant difference at pain relief (NRS score reduced from 8.82 to 2.25) and health related quality of life (ODI score reduced from 49.24 to18.17) was found even immediately after the procedure. The PBKP method enables early mobilization and provides improved functional capability by facilitating pain relief.

The disadvantage of PBKP may be its relatively high cost, due to required equipment, but by immediate pain relief and shorter hospitalization, the use of PBKP may cause long-term healthcare related savings.

CONCLUSION

Percutaneous balloon kyphoplasty have been shown to be effective in controlling pain and improving health related quality of life. This method has the advantage of improving or restoring the vertebral height and kyphotic deformity in osteoporotic or pathological vertebral compression fractures. Competing interests: The authors declare that they have no conflict of interest.

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